

MISSOURI BOARD OF PHARMACY

ANNUAL REPORT

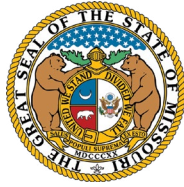


FY 2019

Michael L. Parson, Governor
State of Missouri

Chlora Lindley-Myers, Director
Department of Commerce and Insurance

Sarah Ledgerwood, Interim Director
Division of Professional Registration



Michael L. Parson
Governor
State of Missouri

Sarah Ledgerwood, Interim Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of
Commerce and Insurance
Chlora Lindley-Myers, Director

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Kimberly A. Grinston
Executive Director
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To The Honorable Governor Michael L. Parson:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report which contains the proceedings of the Board for the fiscal year ending June 30, 2019 ("FY 19"). The Board's mission is to protect the public in the regulation of pharmacy practice. The Board of Pharmacy is pleased to report another successful year.

Respectfully yours,
MISSOURI BOARD OF PHARMACY
By:

A handwritten signature in black ink, appearing to read "K A Grinston", written over a horizontal line.

Kimberly Grinston
Executive Director



Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

FY 2019

Board Members

Christian Tadrus, PharmD., President
Douglas Lang, R.Ph., Vice-President
Barbara A. Bilek, PharmD., Member*
James Gray, PharmD., Member**
Colby Grove, PharmD., Member**
Christina Lindsay, PharmD., Member
Pamela Marshall, R.Ph, Member
Anita K. Parran, Public Member
* Term ended December 14, 2018
** Appointed December 14, 2018

Missouri Board of Pharmacy

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Kimberly A. Grinston, J.D., Executive Director

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Executive Summary



This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2018 to June 30, 2019 (FY19). The Board is pleased to announce another successful regulatory year as reflected below:

Board Operations

- The Board held a total of 23 meetings during FY 19, including, five (5) regular session meetings, fourteen (14) conference call meetings and four (4) email ballot meetings. The Board also hosted an additional nine (9) Working Group and Advisory Committee meetings.
- The Board received/responded to approximately 8,205 telephone calls in FY 19 which is consistent with FY 18 data.
- As part of its ongoing efforts to protect patients through voluntary compliance, the Board hosted seven (7) educational seminars, including, six (6) webinars and the 2019 Missouri Patient Safety & Compliance Conference. Educational programs were free and approved for pharmacist continuing education.

Financial Overview

- The Board's total appropriation and authorized transfers for FY19 was \$3,640,789. Of the amount appropriated, the Board expended \$ 2,697,129.45 representing an 18.4% increase primarily attributable to implementation of the Rx Cares for Missouri Program established by § 338.710, RSMo.
- Renewal fees were decreased from \$ 35 to \$ 20 for pharmacy technicians and from \$ 200 to \$ 100 for pharmacists. Despite the decrease, Board revenue increased by 55%.

Licensing Summary

- Total licensees/registrants remained consistent with less than a 1% decrease over all license categories. Specifically, 37,648 individuals/entities were licensed or registered with the Board at the close of FY19 as follows:
 - Drug Distributors (1,336)
 - Drug Distributor Manufacturer Registrants (103)
 - Intern Pharmacists (1,848)
 - Pharmacists- Active & Inactive (11,648)
 - Pharmacists- Temporary (37)
 - Pharmacies (2,765)
 - Pharmacy Technicians (19,742)
- Intern pharmacists experienced the largest decrease in licensing totals with a 16% reduction. The decrease is consistent with lower reported student enrollment for pharmacy schools nationwide, including, the St. Louis College of Pharmacy and the University of Missouri- Kansas City.
- New licenses/registrants decreased by 6.6% with all license categories experiencing a decline.

Complaint Handling

- Approximately 558 complaints/cases were received/opened in FY19 representing a 34% decrease from FY 18. This decrease is primarily attributed to the implementation of new software by the Missouri Department of Revenue resulting in an 86.5% decline in tax suspension cases referred to the Board from the Dept. of Revenue.
- Of the 558 complaints/cases received or opened, 517 were practice-related (93%) while 41 complaints were non practice-related tax compliance cases (7%).

Executive Summary



- The Board issued final dispositions on approximately 675 complaints/cases, including, 40 Department of Revenue tax suspension complaints and 635 non-tax related complaints.
- 504 (79%) of the 635 non-tax related complaint dispositions resulted in no disciplinary action while disciplinary action was taken in 131 cases (21%)

Disciplinary Actions

- The Board issued disciplinary action in 171 cases in FY19, including, 131 practice related disciplinary actions (77%) and 40 non-practice related Department of Revenue tax suspensions (23%). Practice-related disciplinary actions remained consistent with a 2.3% increase from FY 18..
- Pharmacy technician disciplinary actions constituted 62% of all practice-related disciplinary actions taken by the Board. However, technician discipline declined by 5% overall with the majority of disciplined technicians being placed on the Employment Disqualification List.

Inspections

- Board inspectors conducted a total of 1,218 inspections of pharmacies, drug distributors, drug outsourcers and third-party logistics providers, representing a 7% increase.
- The number of entities inspected with no violations increased by 22.6%. Similarly, the number of compliance notices issued after inspection requiring official documentation of corrective measures decreased by 14.4% demonstrating a positive compliance trend. .
- Total Board investigations declined by 9.7% overall.

Compounded Drug Testing

- In 2003, the Board initiated a testing program for drug preparations compounded by pharmacies. 63.6% of products tested in FY19 were satisfactory while 36.4% were unsatisfactory.

Rulemaking

- The Board continued its review of Missouri's pharmacy rules to ensure appropriate and consistent regulation. Thirteen (13) administrative rules were adopted or amended in FY 19.)

Strategic Initiatives

- The Board continued its focus on implementing standards-based regulation that would:
 - 1) Establish standards of practice to ensure patient safety
 - 2) Eliminate unnecessary regulatory requirements and barriers to practice, and
 - 3) Maximize pharmacist skill, training and education to enhance patient access to care.
- The Board's annual strategic planning meeting was held in July 2018 resulting in adoption of the Board's FY19 – FY 20 Strategic Focus Goals as reflected herein.

Executive Summary



Rx Cares for Missouri

- The Board began implementation of the Rx Cares for Missouri Program enacted by the Missouri General Assembly in 2017. FY 19 program activities included initiation of a statewide patient education campaign that delivered an estimated impact of 23,000,000 impressions via print, radio, newspaper, online and social media advertisings.
- The Board issued a Request for Proposal for operation of a statewide medication take-back program that would allow collection of unused or unwanted controlled substances from the public. In compliance with state contracting procedures, a vendor contract was subsequently awarded to Sharps Compliance® to manage and operate the Rx Cares for Missouri Medication Destruction and Disposal Program. The Rx Cares for Missouri Medication Destruction and Disposal Program will provide funding for collection receptacles and medication destruction costs for approved program participants. Participant applications will be available and accepted in FY 20.
- The Board also organized and sponsored the 2019 Missouri Pharmacy Patient Safety Conference in conjunction with the Center for Patient Safety. The conference was free for Board licensees/registrants; Pharmacist continuing education credit was granted.

About the Board



Mission Statement

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
- Licenses only qualified and competent professionals, and;
- Ensures compliance with professional standards and federal and state pharmacy law.

ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration.

MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies and drug distributors;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies and drug distributors; and
- Approval of preceptors and intern training facilities.

Board Operations



The Board held a total of 23 meetings during FY 19, including, five (5) regular session meetings, fourteen (14) conference call meetings and four (4) email ballot meetings. In addition to Board meetings, the following Board Advisory Committee/Working Group meetings were held during FY18:

- Drug Distributor Advisory Committee (1 meeting)
- Hospital Advisory Committee (6 meetings)
- Nuclear Pharmacy Working Group (2 meetings)

Staff

The following staff were employed by the Board at the close of FY19:

Staff

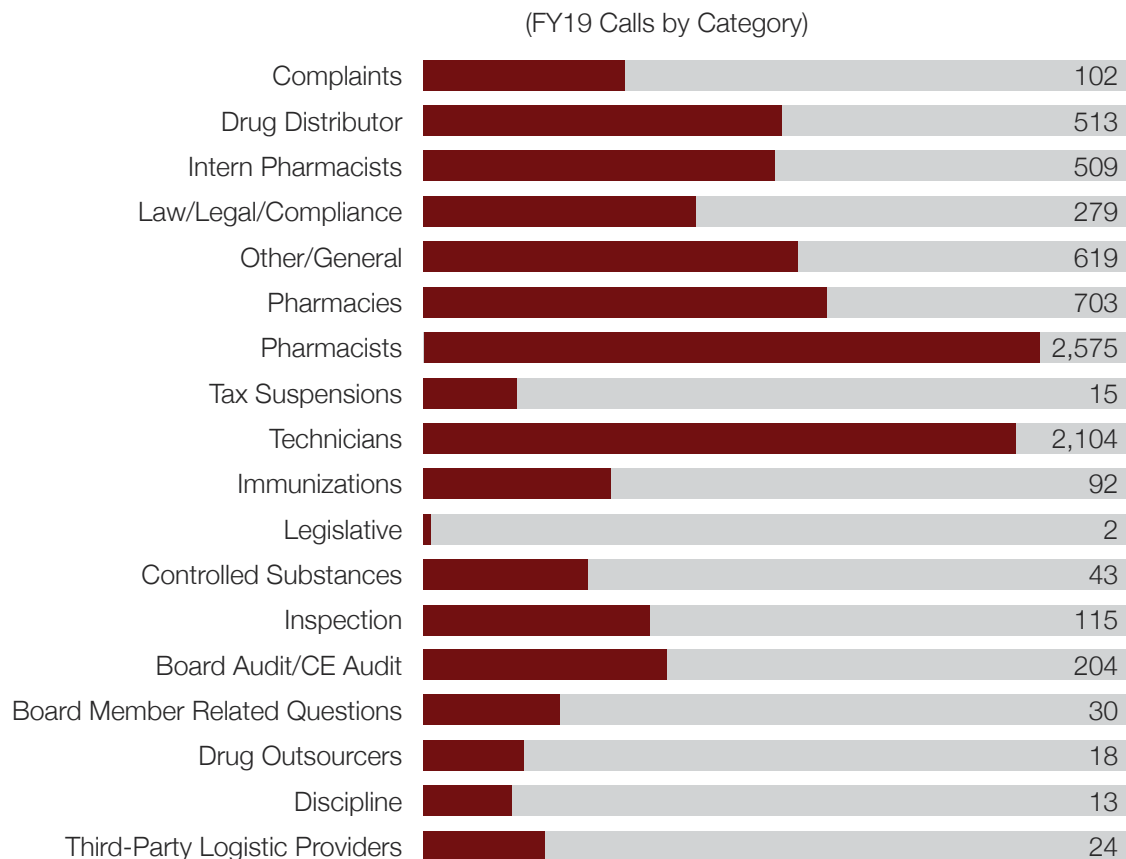
- **Kimberly Grinston, J.D., Executive Director**
- Jennifer Boehm, Administrative Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Jennifer Bax, Senior Office Support Assistant
- Sarah Decker, Compliance Coordinator
- Angela Fulton, Pharmacy Technician Coordinator
- Laura Henke, Pharmacy Coordinator
- Kimberly Hatfield, Pharmacist Coordinator

Inspectors

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Andrea “Andi” Miller, PharmD.
- Scott Spencer, R.Ph.
- Lisa Everett, R.Ph.
- Daniel Vandersand, R.Ph.
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

Office Activities

The Board received/responded to 8,205 telephone calls during FY19 which was consistent with the 8,035 telephone calls received in FY 18. Major call topic areas are identified below:



* Pharmacist category includes licensing, continuing education and audit related questions.



Education/Training

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY19 (participants were awarded free continuing education credit):

- 2018: Legislative Update
- 2018: Sterile Compounding Update
- 2018: Pharmacist Immunization/Administration Update
- 2018: Opioid Dispensing
- 2019: DEA Update with DEA-St. Louis Division Program Manager
- 2019: Pharmacy Technician Compliance Update

The Board also hosted the following live programs:

- 2019 Patient Safety & Compliance Conference (May 9, 2019)

Gold Certificates

The following individuals received Gold Certificates during FY 19 representing fifty (50) years of active service as a Missouri licensed pharmacist:

- | | |
|------------------------|-----------------------|
| • Robert L Alexander | • Melvin E Kohler |
| • Ray F Anderson | • Jack E Littrell |
| • Gene L Beauchamp | • Robert F Manchester |
| • Joseph F Bridges | • John C Martin |
| • Carolyn L Bussen | • James J Naber |
| • William E Clasen | • Frank J Nuber |
| • Ronald Daniel | • Alton R Real |
| • Larry E Desneux | • Margaret A Roberts |
| • Lamoyne Dungan | • Mary A Robinson |
| • Daniel J Feuer | • Richard C Sachan |
| • Gary D Fox | • Robert L Salter |
| • David F Hagedorn | • John E Seibel |
| • Jimmy L Hart | • Jon M Siler |
| • Harvey H Haynes | • Richard W Tiburzi |
| • George I Juenger | • Mary Anne S Toll |
| • Larry L King | • William Z Way |
| • Robert F Klein | • David T Willard |
| • Edward A Klostermann | • Neil A Yant |

Financial Summary



Financial Overview

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2019, was as follows:

Personal Service	\$ 1,200,473
Expense and Equipment	\$ 1,418,418
Criminal History Fund	\$ 5,000
Transfers*	\$ 1,016,898
	<hr/>
	\$ 3,640,789

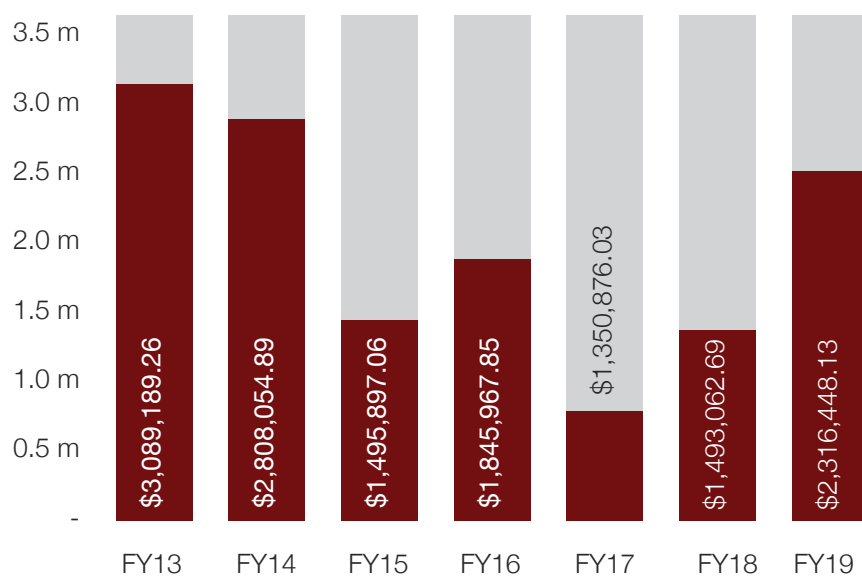
Of the amount appropriated, the Board expended \$ 2,697,129.45 in FY 19 as follows:

Personal Service	\$ 1,136,898.60 (42%)
Expense and Equipment	\$ 642,920.40 (23%)
Transfers*	\$ 917,310.45 (34%)

**Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.*

Revenue Received:

The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that revenue produced does not substantially exceed the cost and expense of administering Chapter 338. In compliance with § 338.070, the Board lowered renewal fees in FY 19 for pharmacy technicians from \$ 35 to \$ 20 and for pharmacists from \$ 200 to \$ 100. Despite the reduction, the Board experienced an overall 55% increase in FY19 revenue as reflected below:



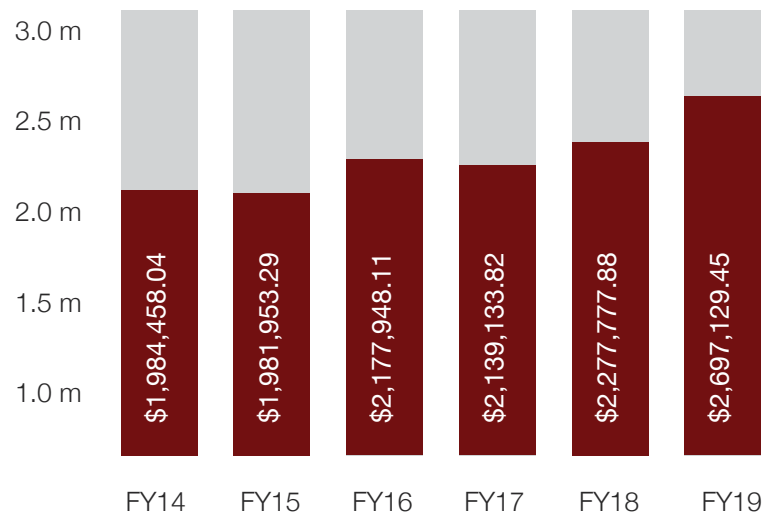
The Board will continue to monitor revenue trends to ensure compliance with § 338.070, RSMo.

Financial Summary



Board Expenditures:

Board expenditures increased by 18.4% which included expenditures for the Rx Cares for Missouri Program established by section 338.710, RSMo, as reflected below:





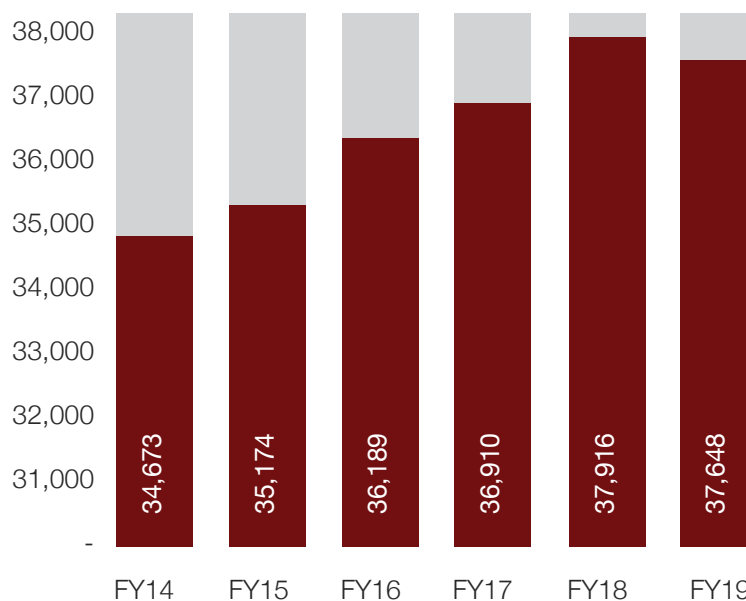
Licensing Summary

Pursuant to Chapter 338, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors.

- The Board's total licensee/registrant count remained consistent with less than a 1% decrease in total licensees/registrants.
- 6,239 new licenses/registrations were issued for all license classes representing a 6.6% decline in total new licenses/registrants (excludes temporary permits)
- Licensing totals at the close of FY19 are provided by classification below:

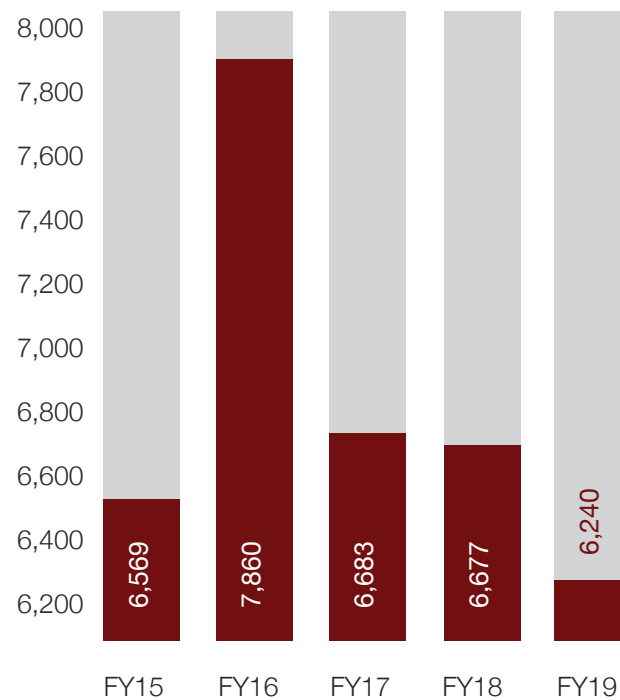
LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,336
Drug Distributor Manufacturer Registrants	103
Intern Pharmacists	1,848
Pharmacists (active and inactive)	11,648
Pharmacists (temporary)	37
Pharmacies (instate, non-resident and temporary)	2,765
Pharmacy Technicians	19,742
Drug Outsources	37
Third-Party Logistics Provider	132
TOTAL	37,648

Total Licensees/Registrants by Fiscal Year





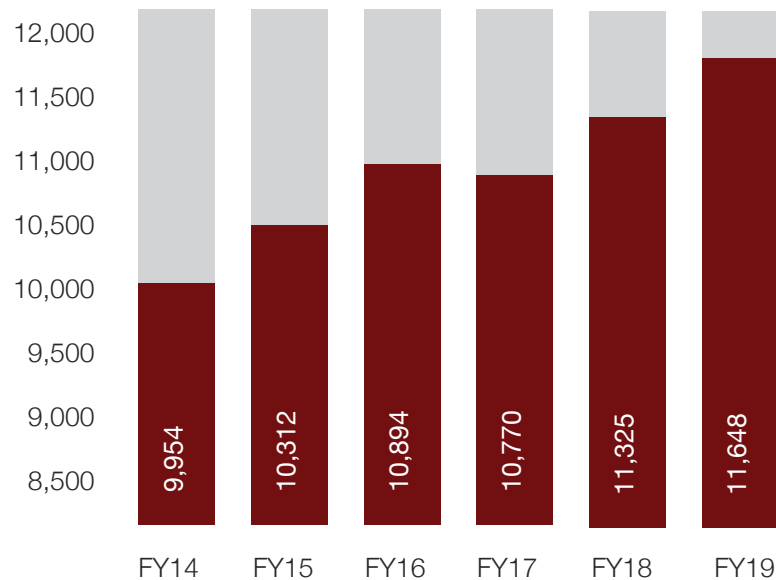
New Licensees/Registrants by FY





Pharmacists:

Total licensed pharmacists remained consistent with a 2.8% increase from FY18.



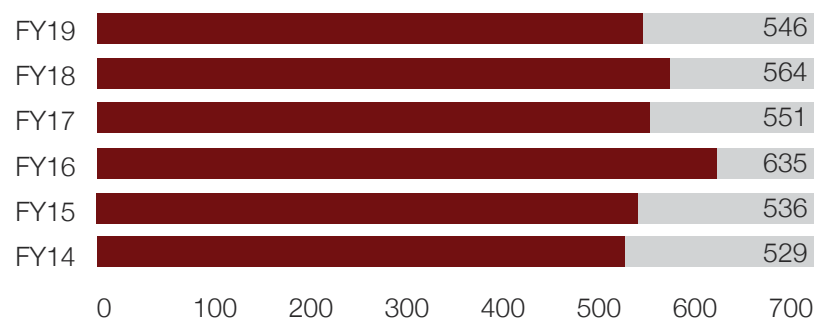
The total number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below. Notably, inactive pharmacists increased by 117% which is consistent with Board data during a pharmacist renewal year as with FY 19. Pharmacists are only allowed to go inactive during the renewal period.

Active Licensees	10,909
Male	4,731
Female	6,178
Inactive Licensees	739
TOTAL LICENSED PHARMACISTS	11,648

***Inactive pharmacists are not authorized to practice in Missouri but remain licensed.*

Number of New Pharmacist Licenses Issued

A 3% decrease in newly licensed pharmacists occurred in FY19 as reflected below:

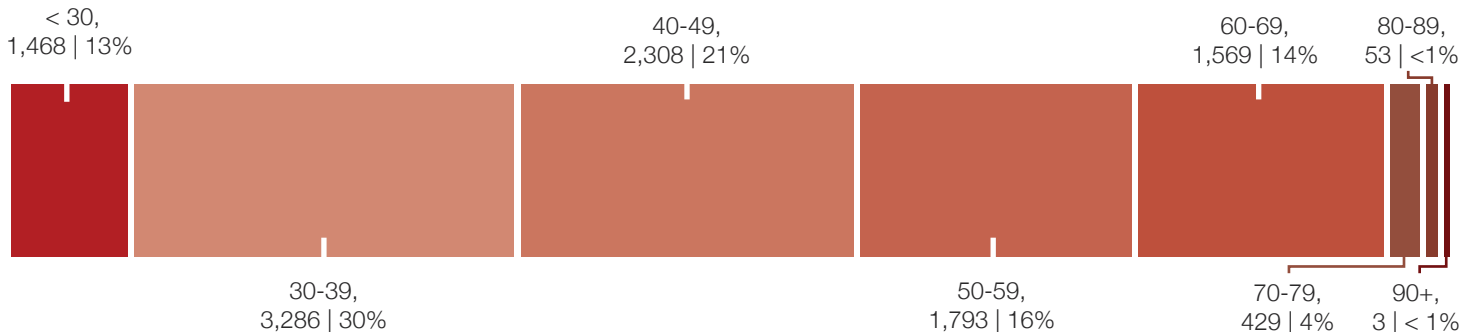




Active Pharmacists By Age Group (Resident and Non-Resident) [#,%]

No significant changes occurred in the number of active pharmacists categorized by age. Forty percent (40%) of licensed Missouri pharmacists are age 39 and under with the remaining sixty percent (60%) at age 40 or above.

(Pharmacist Distribution by Age)



Pharmacists Residing in Missouri

No significant changes occurred in actively licensed resident vs. non-resident pharmacists. Approximately 62% of pharmacists licensed by the Board reported a Missouri address as reflected below:

Resident Pharmacists	6,710
Non-Resident Pharmacists	4,199
Total Missouri Resident Pharmacists	10,909

Administration & Immunizations:

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri licensed physician, upon filing a Notification of Intent with the Board. At the end of FY 19:

- 3,024 pharmacists were authorized to administer medication by prescription.
- 3,293 pharmacists were authorized to administer immunizations by protocol.

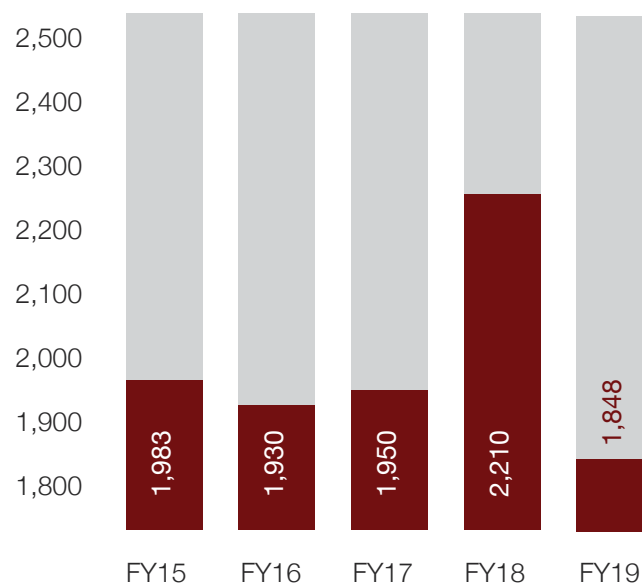
Medication Therapy Services:

Section 338.010, RSMo, authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 3,057 pharmacists held a MTS certificate at the end of FY19 representing an 4% increase from FY18.



Intern Pharmacists

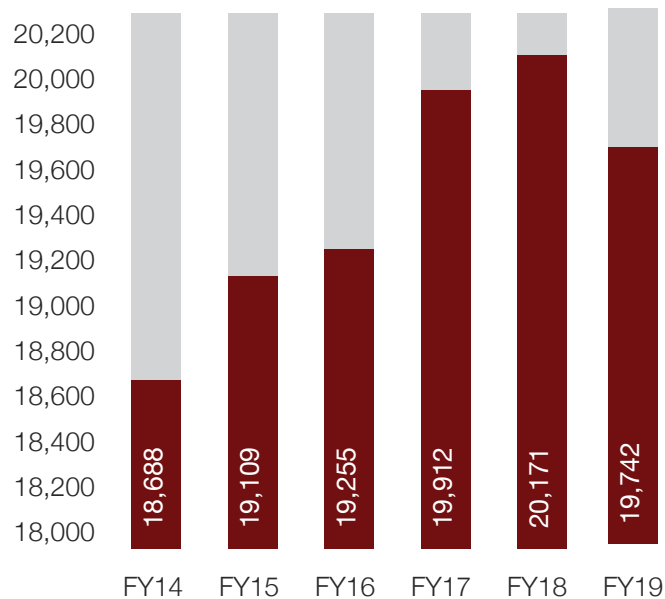
Licensed intern pharmacists decreased by 16% which appears to be consistent with lower student enrollment numbers reported for pharmacy schools nationwide, including, the St. Louis College of Pharmacy and the University of Missouri- Kansas City.





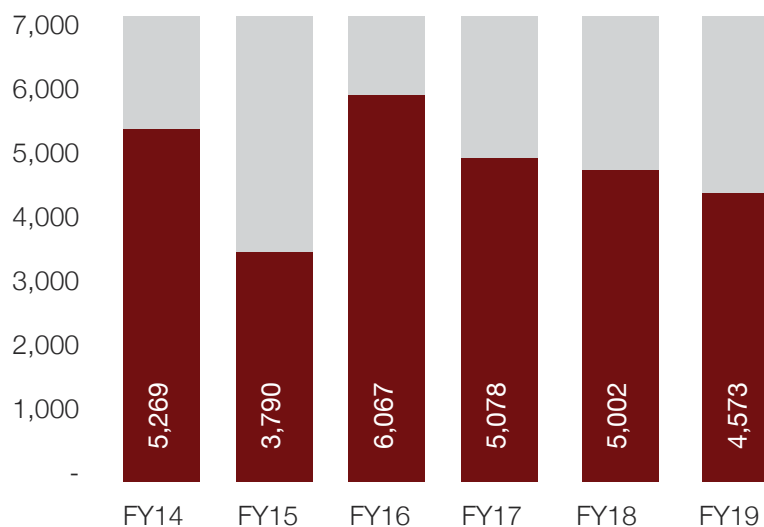
Pharmacy Technicians:

Similar to other license categories, the number of registered pharmacy technicians experienced a slight decrease of 2.1% as reflected below:



New Pharmacy Technician Registrations Issued

Newly registered pharmacy technicians decreased by 8.6% representing the third fiscal year with a decrease:



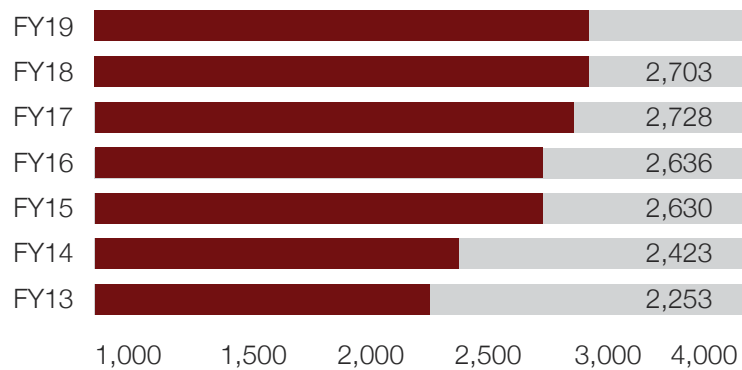


Pharmacy Summary:

PHARMACY PERMIT TOTALS	
Instate Pharmacies	1,538
Non-Resident Pharmacies	1,226
Temporary Pharmacies	1
TOTAL	2,765

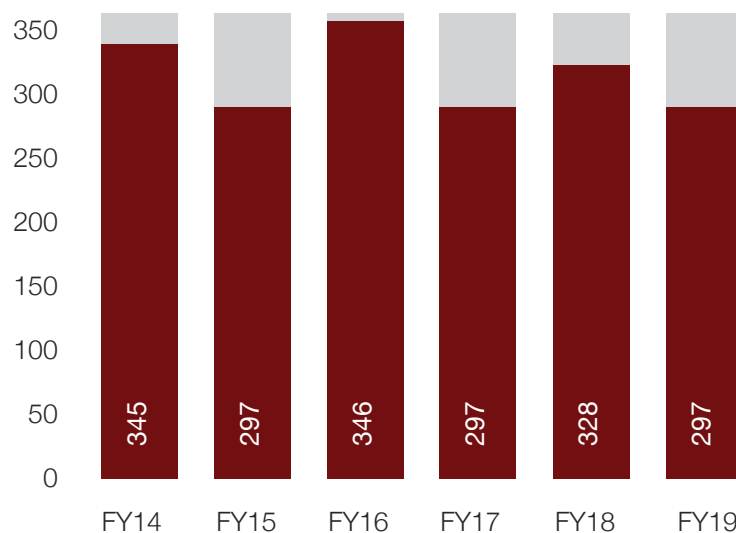
Pharmacy Permitholders By Fiscal Year

Total licensed pharmacies increased by 2% to 2,765 pharmacies as reflected below:



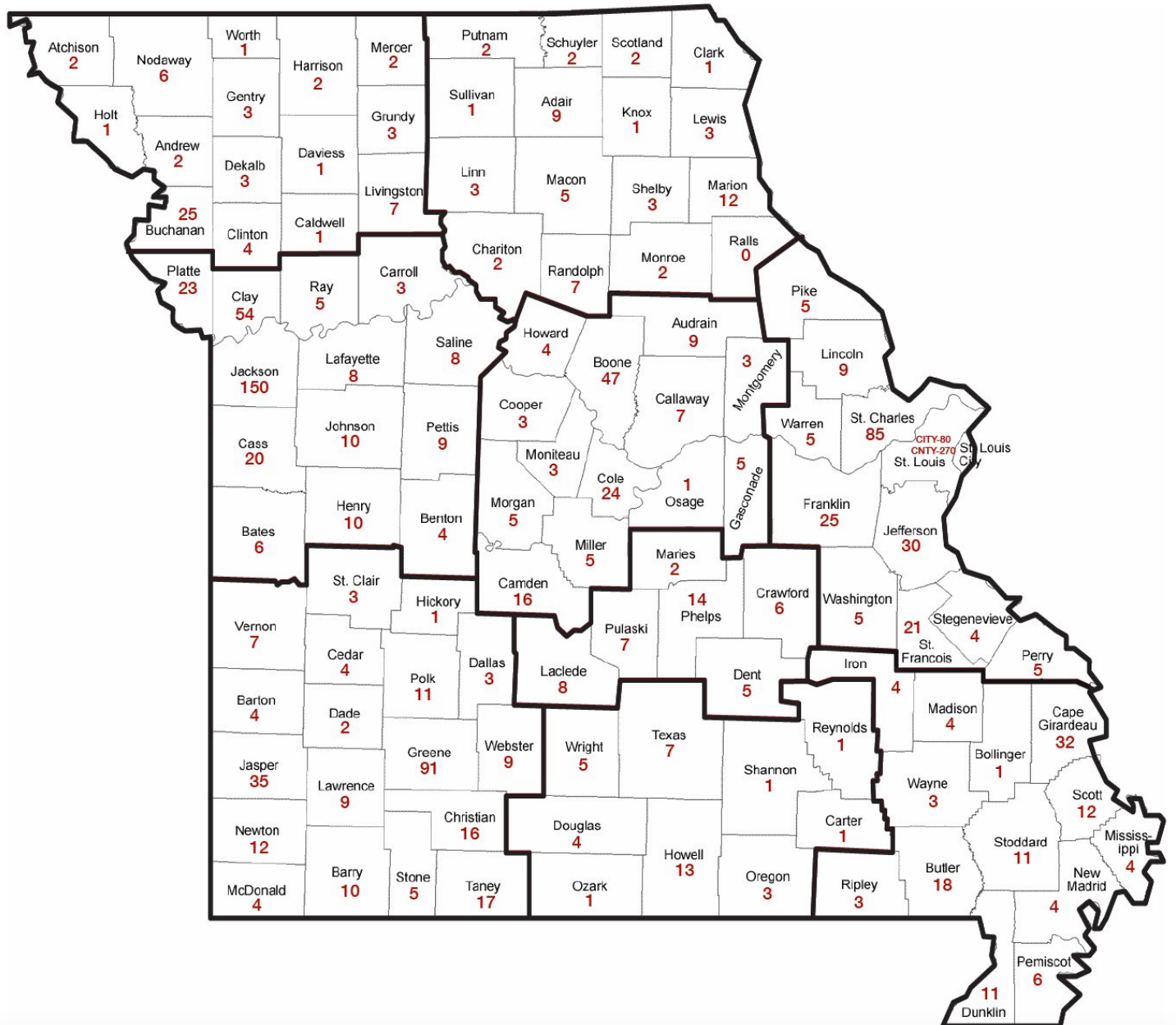
New Pharmacy Permits Issued

New pharmacy permits decreased by 9.4% in FY19 which is consistent with the Board's licensing history in non-renewal fiscal years for pharmacies:





Missouri Pharmacies by County



Statistics to Note:

- Number of counties with 0 pharmacies: 1 (Ralls County)
- Number of counties with ≤ 10 pharmacies: 87
- Number of counties with 100+ pharmacies: 2 (St. Louis & Jackson County)
- 11 counties experienced a decrease in pharmacies in FY19 (Boone, Buchanan, Cass, Clay, Dunklin, Franklin, Grundy, Jefferson, Oregon, Ozark, Ripley) while 11 counties/areas increased in pharmacies (Carroll, Christian, Clinton, Jackson, Johnson, Marion, Mercer, St. Charles, St. Louis City, St. Louis County, Saline)

Licensing

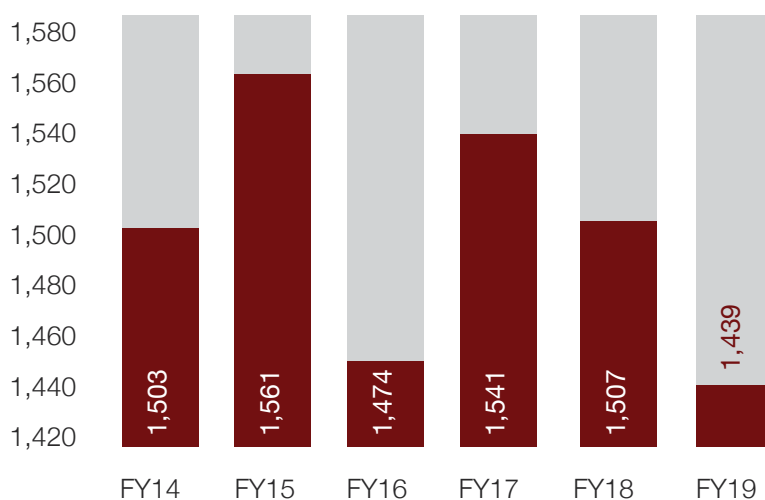


Drug Distributor Summary:

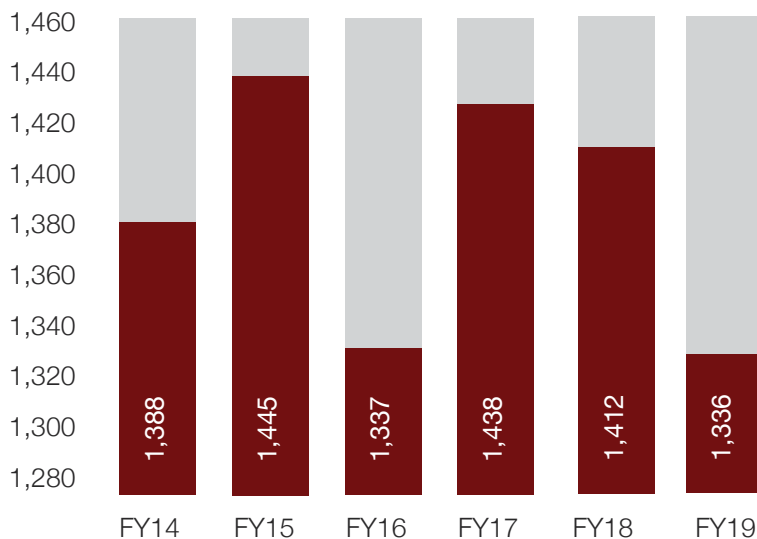
All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug-related devices into Missouri must hold a Missouri drug distributor license. Missouri law was amended in 2018 to add a separate license category for drug outsourcers and third-party logistics providers. Previously, drug outsourcers and third-party logistics providers were required to have a drug distributor license. Currently licensed drug distributors were granted the option to convert to a drug outsourcer or third-party logistics provider in FY19 at no fee.

TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

The total number of licensed drug distributors and drug distributor registrants decreased by 4.5% to 1,439 licensees/registrants (1,336 drug distributors and 103 drug distributor registrants). This decrease is likely attributable to drug distributors converting to the newly enacted drug outsourcer and/or third-party logistics provider license.



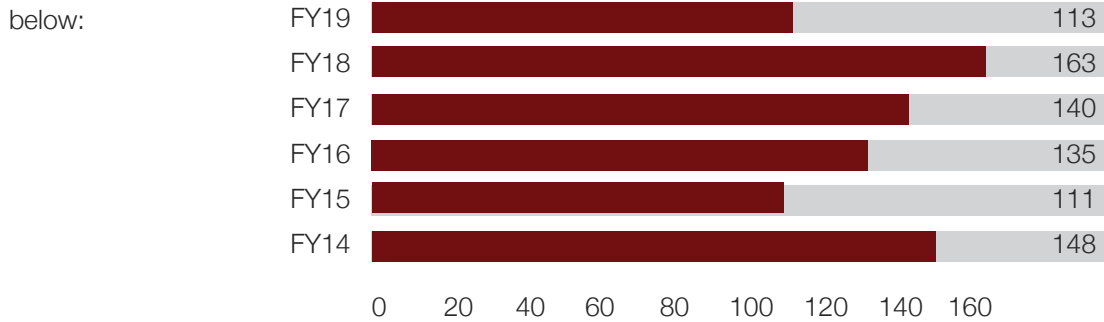
TOTAL DRUG DISTRIBUTORS BY FY



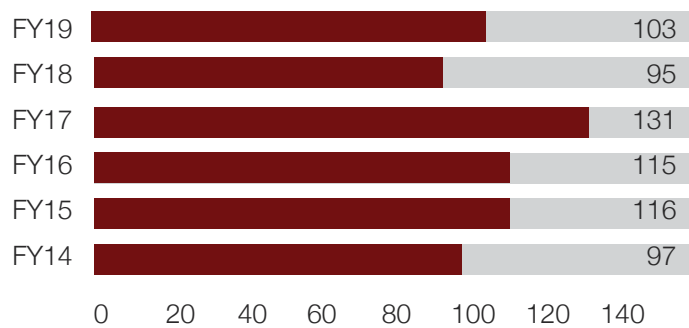


NEW DRUG DISTRIBUTORS LICENSED

A 30.6% decrease occurred in newly licensed drug distributors as reflected below:

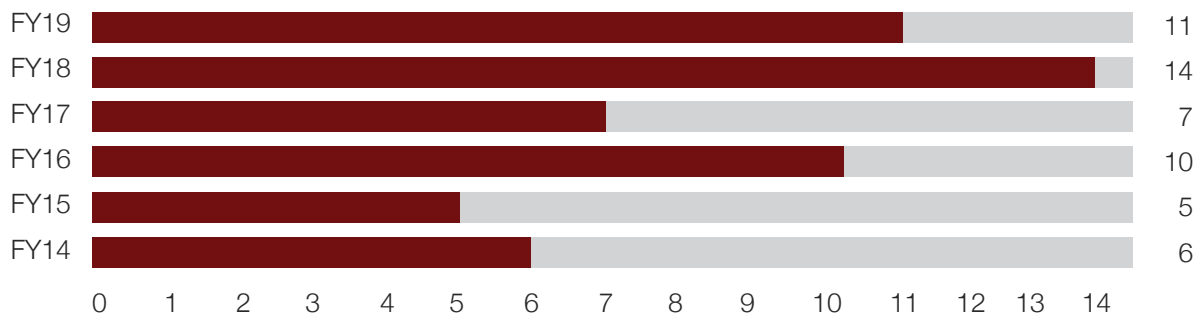


TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY



NEW DRUG DISTRIBUTOR REGISTRANTS

The number of new drug distributor registrants remained historically low:



DRUG OUTSOURCERS/THIRD -PARTY LOGISTICS PROVIDERS

Chapter 338 was amended in 2018 to add a drug outsourcer and third-party logistics provider license class. The board began issuing licenses for both classes in FY19 as reflected below:

- Drug Outsourcers- 37
- Third-Party Logistics Provider- 132

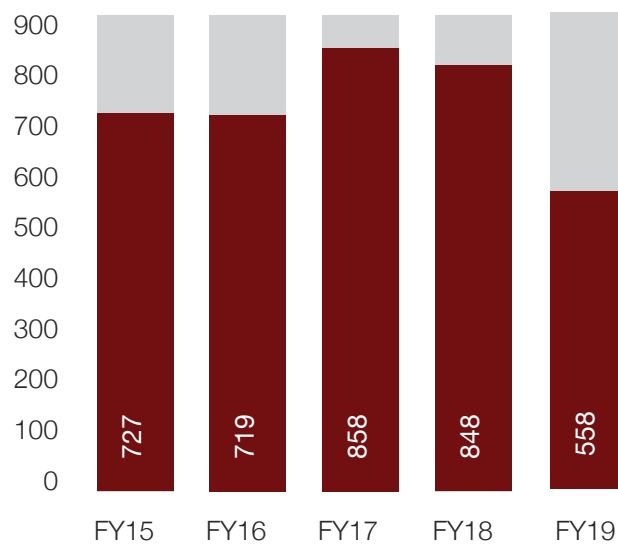
Complaint Summary



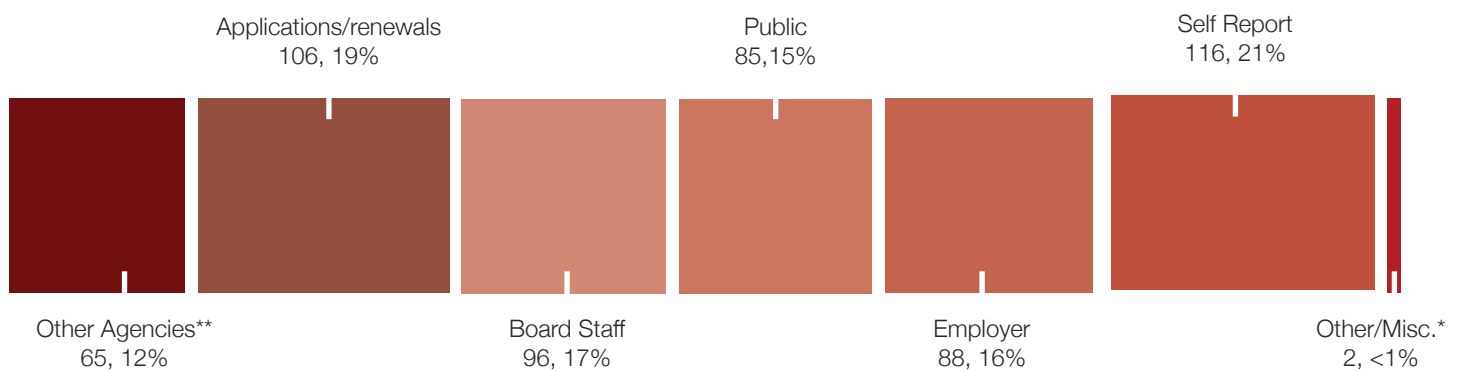
Complaint Summary

All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 558 new complaints in FY 19 representing a 34% decrease from FY18. Of the 558 complaints received/opened, 517 complaints were practice-related complaints (93%) while 41 complaints were non-practice related Missouri Department of Revenue tax compliance cases (approx. 7%). The decrease in complaints is primarily attributed to a 86.5% decline in Missouri Department of Revenue tax compliance cases due to new software implementation by the Department of Revenue that resulted in fewer referred tax suspensions.

Complaints Handled by FY



Complaints by Source



** Includes Dept. of Revenue tax suspensions (41 cases)

Complaint Summary



FY19 COMPLAINTS BY CATEGORY (Non-Tax Related)

Advertising/Marketing	2
Alcohol Use/Impairment	7
Compounding	8
Confidentiality	1
Criminal History	7
Dispensing Error	28
Drug Diversion	21
Drug Use/Impairment	13
Expired Drugs in Active Inventory	4
Fraudulent Prescription	1
Immunization/Administration	10
Improper Controls	91
Improper/Unauthorized Dispensing	16
Inspection Violations	1
Insurance/Billing	4
Licensure Applicant	93
Misbranding	1
Misconduct/Sexual Misconduct	4
Other	56
Pharmacy Permit Violations	5
Previous Discipline/Disciplinary Action in Another State	147
Security	1
Theft (Non-Drug)	14
Unlicensed Activity	16
Unprofessional Conduct	3
Unsanitary Facility	2
Violation of Discipline	2

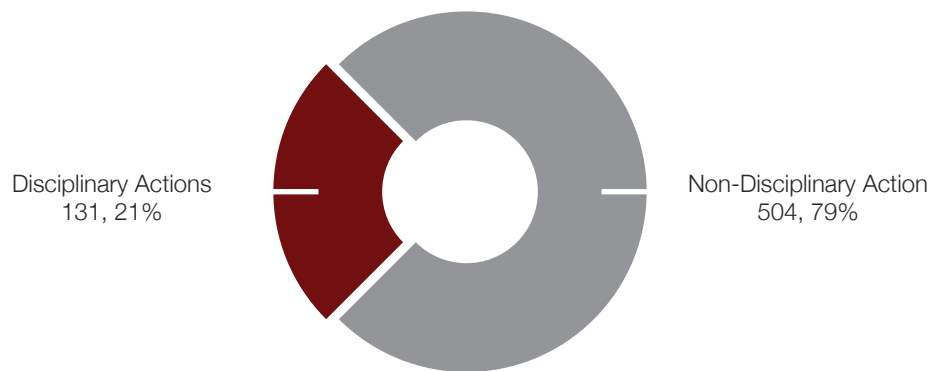
Complaint Summary



COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 675 complaints/cases in FY19 which included 40 Department of Revenue tax suspension complaints and 635 non-tax related complaints, representing a 20% decrease from FY 18. This decrease is largely attributed to an 86.5% decline in tax suspension cases referred by the Missouri Department of Revenue pending implementation of Revenue's new software system. The 635 non-tax related cases were disposed of as follows:

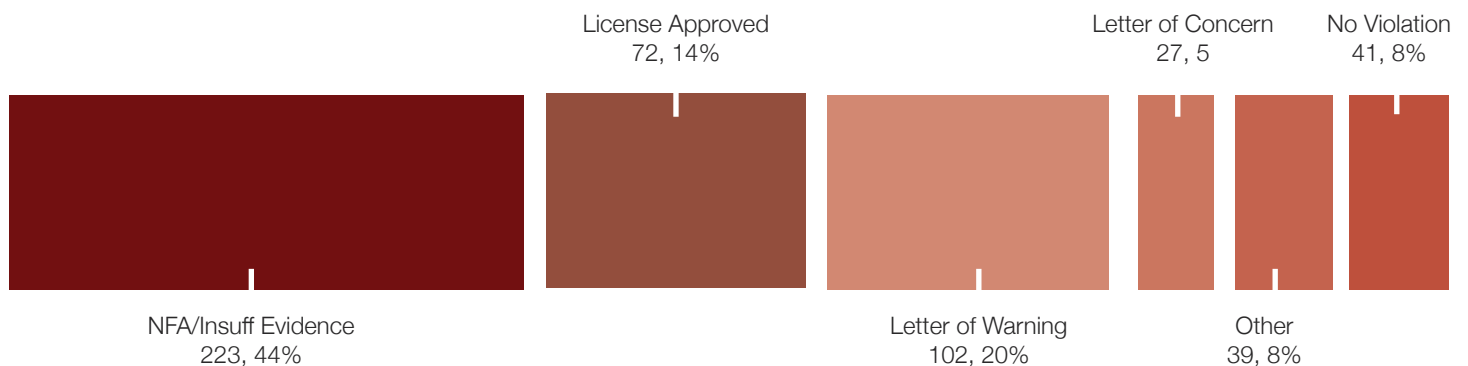
(Non-Tax Related Complaint Dispositions)



*The 674 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY19. As a result, the number of complaints disposed of in FY19 will not equal the number of new complaints received.

SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 504 non-tax related complaints closed without disciplinary action in FY19: (see Disciplinary Action section for complaints closed with disciplinary action)



* Other: Approved to Test (1), Closed (24), Closed but Flagged for Future Review (12), Discipline Modification Approved (1), Voluntary Surrender (1)

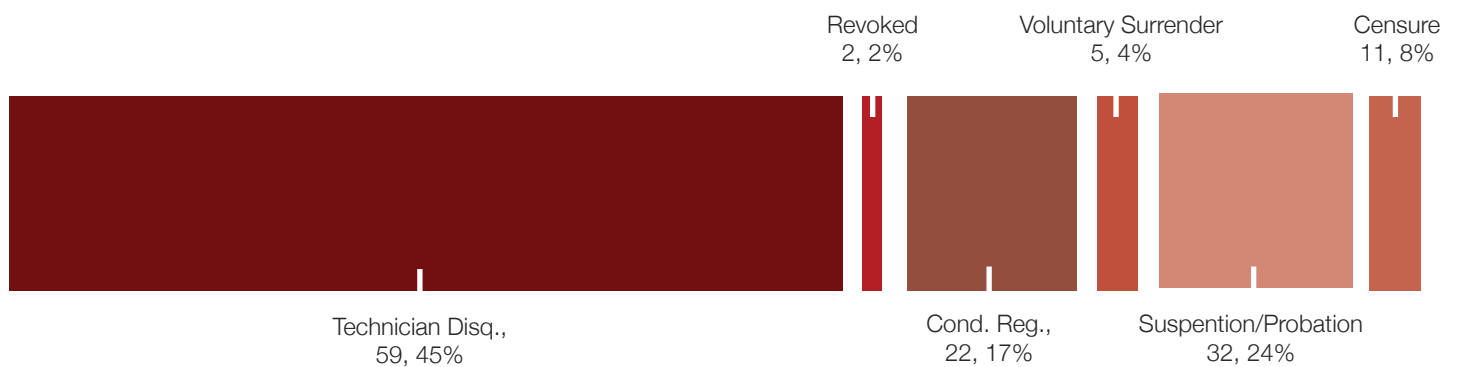
Disciplinary Actions



Summary of Disciplinary Action

The Board issued disciplinary action in 171 cases in FY19. One-hundred and thirty one (131) practice related disciplinary actions were issued (77%) while the remaining 40 cases involved non-practice related Department of Revenue tax suspensions (23%). Practice-related disciplinary actions were consistent with FY18 with a 2.3% increase.

The following disciplinary action was taken in the 131 practice-related disciplinary actions issued in FY 19:



DISCIPLINARY ACTIONS BY CATEGORY

Drug Distributors Probated	6
Drug Outsourcers Probated	1
Intern Licenses Revoked	1
Pharmacist Licenses Censured	1
Pharmacist Licenses Probated	10
Pharmacist Licenses Revoked	1
Pharmacist Licenses Voluntarily Surrendered (Treated as Discipline)	4
Pharmacy Permits Probated	15
Pharmacy Permits Voluntarily Surrendered (Treated as Discipline)	1
Technician Registrations Suspended under § 324.010 (tax purposes)	40
Technicians Disqualified	59
Technicians Placed on Conditional Employment	22
TOTAL	161

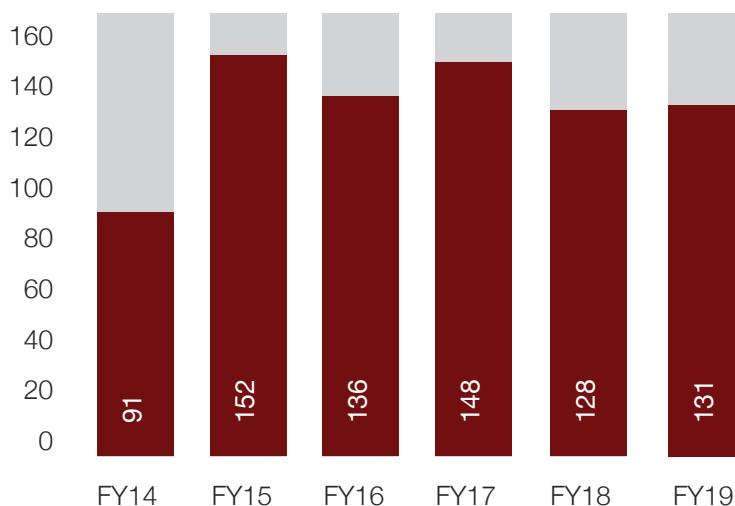
Disciplinary Actions



PRACTICE RELATED DISCIPLINARY ACTIONS *

Eighty-One (81) pharmacy technicians, 26 pharmacists, 1 intern pharmacist, 1 drug outsourcer, 16 pharmacies and 6 drug distributors were disciplined for practice-related issues during FY19, representing a 2.3% increase from FY18.

(Total Practice-Related Disciplinary Actions by FY)

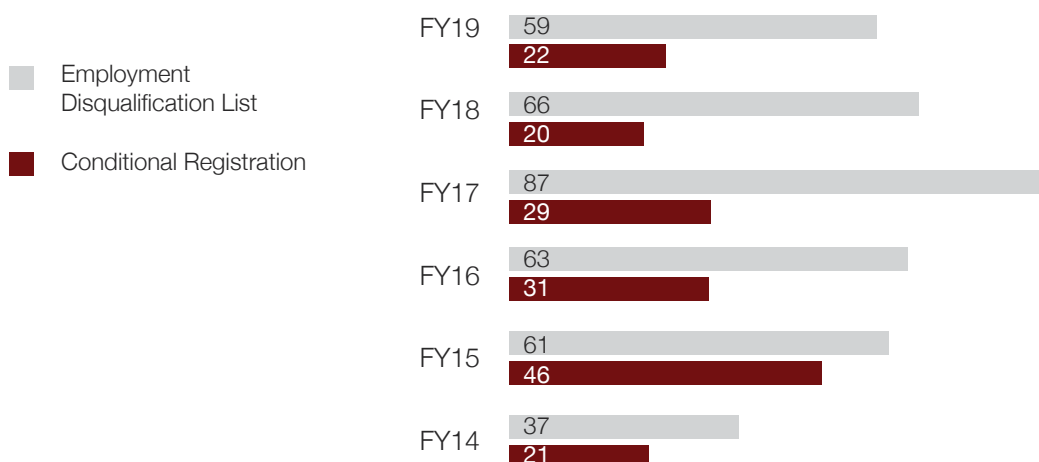


* Does not include tax suspensions pursuant to § 324.010, RSMo.

PHARMACY TECHNICIAN DISCIPLINE

Eighty-one (81) pharmacy technicians were disciplined for practice-related reasons, comprising 62% of all practice-related disciplinary actions issued by the Board. However, total technician disciplinary actions declined by 5% as reflected below:

(Practice Related Pharmacy Technician Discipline by FY)



Disciplinary Actions



GROUND FORS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION

(Cause for EDL / # Disciplined)

- Alcohol Use/Prior Impairment (2)
- Criminal History (9)
- Diversion (11)
- Fraud (1)
- Misconduct/Unauthorized Dispensing (1)
- Illegal Drug Usage/Positive Drug Test (20)
- Impairment/Refusal to Take Drug Test (2)
- Theft (Non-Drug Related) (13)

GROUND FORS FOR TECHNICIAN CONDITIONAL REGISTRATION

(Cause for CR/ # Disciplined)

- Criminal History (10)
- Improper/Prior admitted drug use (7)
- Unlicensed activity (Working while suspended/expired) (4)
- Violation of Discipline (1)

PHARMACIST DISCIPLINE BY FY:

Pharmacist practice-related discipline increased by 24% although the total number of pharmacy disciplinary actions remained historically low:

	FY14	FY15	FY16	FY17	FY18	FY19
Censure	7	5	6	6	3	11
Probation	6	5	14	13	15	10
Suspension	0	2	0	0		0
Suspension/Probation	2	4	4	0	1	0
Revocation	2	1	3	1	1	1
Voluntary Surrender (treated as discipline)	--	--	--	4	1	4
TOTAL	17	17	27	24	21	26

Disciplinary Actions



PHARMACY DISCIPLINE BY FY

Pharmacies discipline remained consistent as reflected below:

	FY14	FY15	FY16	FY17	FY18	FY19
Censure	2	9	4	0	4	0
Probation	9	12	8	7	9	15
Revocation	0	0	2	0	0	0
Voluntary Surrender	0	0	0	0	2	1
TOTAL	11	21	14	7	15	16

DRUG DISTRIBUTOR DISCIPLINE BY FY

Similar to pharmacies, drug distributor discipline increased although the overall number of disciplinary actions remained historically low:

	FY14	FY15	FY16	FY17	FY18	FY19
Censure	0	0	0	0	0	0
Probation	0	3	1	0	4	6
Voluntary Surrender	0	0	0	0	0	0
TOTAL	0	3	1	0	4	6

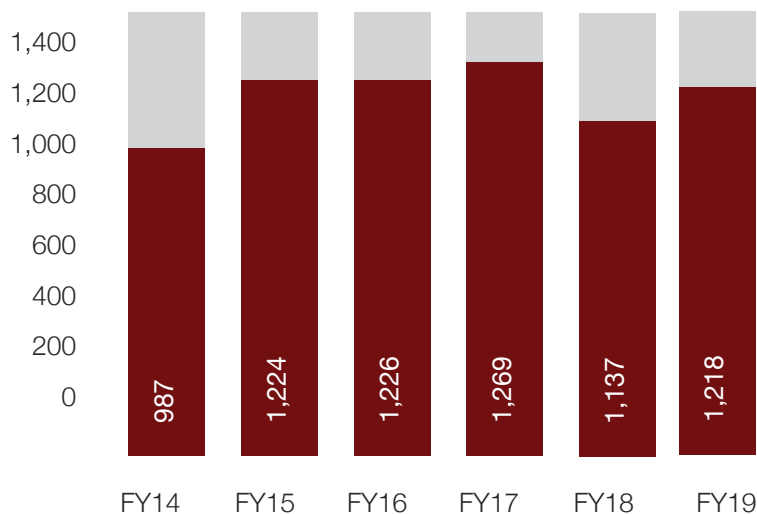


Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies, drug distributors drug outsourcers and third-party logistics providers. Board inspectors also conduct investigations as assigned.

- 1,218 regulatory inspections were conducted in FY 19 representing a 7% increase in inspection activities.
- 1,061 pharmacy, 154 drug distributor, 1 third-party logistics provider and 2 drug outsourcer inspections were conducted. Thirty- two (32) drug distributors were exempt from inspection as state facilities or as authorized by 20 CSR 2220-5.040 for facilities inspected by the U.S. Food and Drug Administration.
- The Board continues to inspect all sterile compounding pharmacies annually.
- A total of 232 investigations were completed in FY19 by Board staff/inspectors, representing a 9.7% decrease.

FY 19 - Pharmacy/Drug Distributor Inspection Summary



INSPECTION FINDINGS

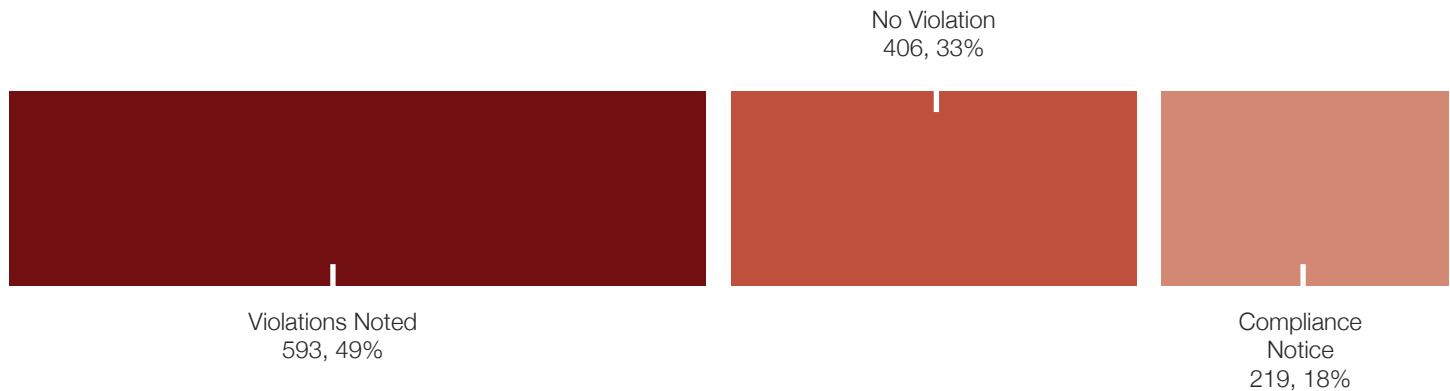
At the conclusion of an inspection, the inspector may initiate one of the following resolutions:

- **Observation Report:** Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- **Compliance Notice:** Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- **Quality Assurance Report:** Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- **Investigation:** An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.



FY19 INSPECTION RESULTS*

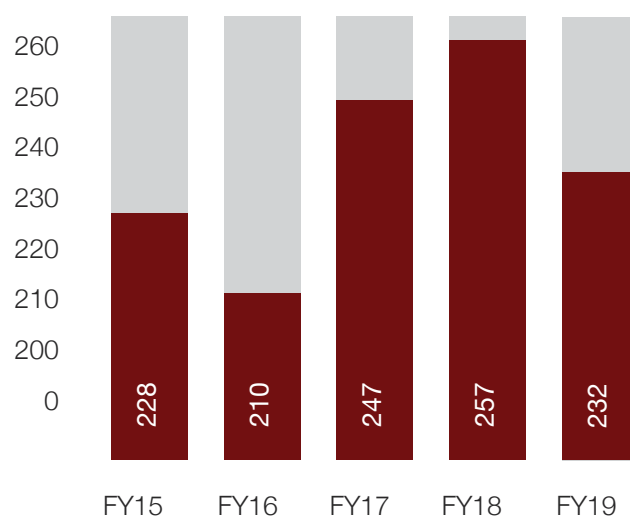
Approximately 67% of Board inspections resulted in violations noted or a compliance notice being issued as reflected below:



The number of entities inspected with no violations increased by 22.6% while the number of compliance notices issued after inspection requiring official documentation of corrective measures decreased by 14.4% demonstrating a positive compliance trend.

** Includes inspection results for follow-up inspections and investigations.*

FY 19 INVESTIGATION SUMMARY



Compounded Drug Testing



Testing Summary

In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2019:

Dosage Form	Tests Performed
Capsule	14
Chewable Tablet	1
I.V. Solution	2
Inhalation Solution	2
Injection	5
Oil	1
Oral Suspension	10
Sublingual Tablet	1
Suppository	2
Topical Cream/Ointment	10
Topical Gel	2
Troche	4
Vaginal Cream	1

Test Results	Tests Performed	Percentage
Satisfactory	35	63.6%
Unsatisfactory	20	36.4%
Total	55	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 53.7% to 193.9%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

Drugs With Unsatisfactory Results	
Amiodarone oral suspension	Meloxicam/Topiramate/Tramadol/Lidocaine/Prilocaine topical cream
Amlodipine oral suspension	Naltrexone capsule
Atropine oil	Progesterone capsule
Biest capsule	Sildenafil suppository
Biest/DHEA/Progesterone/Testosterone oral suspension	Sildenafil chewable tablet
Calcipotriene/Fluorouracil topical cream	Sildenafil Citrate sublingual tablet
DHEA/Pregnenolone/Progesterone capsule	Testosterone capsule
Ketoprofen/Lidocaine topical cream	Triest/DHEA/Progesterone troche
Lidocaine HCl/Nifedipine topical cream	



Rule Changes

The Board continued to review Missouri's pharmacy rules to ensure appropriate and consistent regulation. The following rules were promulgated by the Board in FY19:

Promulgated Rules

PROMULGATED RULES		
20 CSR 2220-2.120	Transfer of Prescription or Medication Order Information	Clarified and updated Missouri's prescription/ medication order transfer requirements
20 CSR 2220-2.200	Sterile Compounding	Updated and clarified medication recall procedures
20 CSR 2220-2.400	Compounding standards of practice (Emergency Rule)	Authorized pharmacies to provide non- patient specific compounded preparations to a Missouri licensed veterinarian for animal use
20 CSR 2220-2.400	Rx Cares for Missouri Program	Established a Board funded statewide medication destruction program
20 CSR 2220-2.085	Electronic Prescription and Medication Orders	Streamlined and updated requirements for electronic prescriptions/medication orders
200 CSR 2220-6.050	Administration by Vaccines per Protocol	Reduced and updated regulatory requirements for pharmacists administering vaccines under protocol with a Missouri physician
20 CSR 2220-8.010*	Definitions	Establishes Definitions for the regulation of third-party logistic providers and drug outsourcers
20 CSR 2220-8.020*	Licensing Requirements	Established licensing requirements for drug outsourcers and third-party logistics providers
20 CSR 2220-8.030*	Nonresident Third Party Logistics Providers/ Drug Outsourcer Facilities	Established licensing requirements for non-resident third party logistics providers and drug outsourcers
20 CSR 2220-8.040*	Standards of Operations (Drug Outsourcers)	Established standards of operations for drug outsourcers licensed by the Board
20 CSR 2220-8.045*	Standards of Operations	Established standards of operations for third-party logistics providers licensed by the Board
20 CSR 2220-8.050 *	Inspection Exemptions	Established inspection standards and inspection exemption allowances for drug outsourcers and third-party logistics providers
20 CSR 2220-8.060*	Termination of Business	Establishes guidelines for drug outsourcers and third-party logistics providers operating in the state

*Rules implemented 2018 legislation.



Strategic Initiatives

As part of its regulatory mission, the Board continued its efforts to protect Missouri citizens and enhance Board operations. The Board approved/sponsored the following in FY 19:

LEGISLATIVE PROPOSALS

The following legislative proposals were approved by the Board for the 2018-2019 legislative session:**

- Pharmacy Pilot Projects: Would allow the Board to approve pharmacy pilot projects related to technology assisted verification or remote medication dispensing to enhance patient care or safety, improve patient outcomes or expand access to pharmacy services.
- Prescription Receipt: Would allow pharmacists to physically accept a prescription at a non-pharmacy location (e.g., health clinic, medical office).
- Alternative Compliance Agreement: Would allow the Board to enter into public voluntary compliance agreements in lieu of discipline.
- Pharmacy Technician Training and Education: Would establish minimum training and education requirements for pharmacy technicians to protect the public and ensure minimum competency.
- Pharmacist Well-Being Program: Would update provisions governing the Pharmacist Well-Being Program for impaired licensees and facilitate implementation of the Program in Missouri.

** Legislative proposals are subject to Governor approval.

Compliance:

The Board continued its campaign to encourage and promote compliance and patient safety. The Board sponsored/hosted the following free continuing education programs in FY19:

- 2019 Missouri Pharmacy Patient Safety Conference- Columbia (10-24-19) See Rx Cares for Missouri section.
- 2018 Legislative Update*
- 2018 Sterile Compounding Update*
- 2018 Pharmacist Immunization/Administration Update*
- 2018 Opioid Dispensing*
- 2019 DEA Update with DEA-St. Louis Division Program Manager*
- 2019 Pharmacy Technician Compliance Update*

** Webinar

Strategic Initiatives



The Board held its annual strategic Planning Meeting in July 2018 and adopted the following FY19 Strategic Focus Goals. The Board also continued its focus on implementing standards based regulation that would increase access to pharmacy services by:

- 1. Establishing standards of practice to ensure patient safety
- 2. Eliminating unnecessary regulatory requirements, and
- 3. Maximizing pharmacist skill, training and education to enhance patient access to care.

FY 19 BOARD STRATEGIC FOCUS PLAN:

Licensee Education & Training	<p>Continue to enhance licensee education, training & outreach:</p> <ol style="list-style-type: none">1. Update the Missouri Practice Guide by August 28, 2018, and annually thereafter. Provide complimentary copies to each Missouri pharmacy every two (2) years.2. Increase subscribers to the Board's electronic alerts & newsletters. Explore ways to incorporate subscribing as part of the initial application and renewal process.3. Continue current compliance webinars. Recommended future topics include inspection violations, top compliance issues/trends and BNDD updates.4. Increase print and electronic licensee communications, including, mailing of Board newsletters and informational materials.5. Provide information on Board educational materials on initial licensure.6. Collaborate with Missouri pharmacy related associations to promote/advertise Board activities and educational opportunities via their membership communication tools.7. Provide additional online training material within current staff capability8. Develop draft rule language that establishes tiered late continuing education fees based on the violation. Educate licensees on continuing education options and requirements.
Well-Being Program	<ol style="list-style-type: none">1. Create online resource center containing Missouri treatment resources2. Research well-being programs in neighboring states to identify collaboration opportunities3. Identify alternative treatment and counseling opportunities that could be provided by the Board4. Have Board members attend the APhA impairment training program in Utah. Require attendance in impairment related Board disciplinary orders, as deemed appropriate.5. Explore opportunities to discuss state well-being initiatives at the NABP District 6 meeting.



Quality Assurance	<ol style="list-style-type: none"> 1. Establish a Board sub-committee to research and make recommendations on ways to incorporate and promote effective continued quality improvement and Just Culture measures in pharmacy. The Sub-Committee's review should include other state initiatives, recommendations from the Board's 2015 Patient Safety Committee and other evidence-based materials/studies deemed appropriate. 2. Provide Just Culture or equivalent licensee education.
Board Meeting Procedures	<p>Continue to identify ways to enhance and streamline Board meeting procedures. The following recommendations were made:</p> <ul style="list-style-type: none"> • Implement recommended staff delegation list with Board approved modifications. • Limit the size of agenda addendums to allow sufficient time for review. Establish addendum cutoff dates. • Research providing Board member electronic equipment to enhance Board agenda review, including, providing Board member laptops or tablets • Explore alternative electronic meeting options such as WebEx • Send e-mail ballots on a designated day of the week and allow seven (7) days to respond. Notify Bd members of e-mail ballots at both their public and private e-mail addresses. • Review agenda procedures in October after implementation of expanded delegation authority.
Board Administrative Operations	<ul style="list-style-type: none"> • Continue to identify and provide Board inspector and staff training opportunities. • Increase employee cross-training • Continue to review and update Board internal policies and procedures • Discuss/develop employee succession plan • Research authorized online recruitment options and resources.
Patient Counseling	<ul style="list-style-type: none"> • Develop and implement a patient counseling educational campaign for both pharmacists and patients that would: <ol style="list-style-type: none"> 1) Increase pharmacy awareness of effective ways to offer and provide counseling 2) Increase patient awareness of their right to request counseling and 3) Promote better pharmacist-patient communication • Promote patient counseling education campaign as part of American Pharmacists Month in October.
Board Member Development	<ul style="list-style-type: none"> • Research and provide Board member training on industry changes/topics that may impact practice. Training may include written materials or speaker presentations during Board meetings.
Standards-Based Regulation	<ul style="list-style-type: none"> • Develop and implement a roadmap for incorporating a standards-based regulatory approach that would allow pharmacists to maximize their scope of practice • Work with legal counsel to identify required statutory changes and regulatory opportunities/challenges • Gather licensee/stakeholder feedback

Rx Cares for Missouri Program



In 2017, the Missouri General Assembly enacted the Rx Cares for Missouri Program (the Rx Cares Program) within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse and diversion in Missouri. The Board was appropriated funding for the Program in FY19 and initiated implementation of the Rx Cares Program in consultation with the Missouri Department of Health and Senior Services as required by § 338.710, RSMo. The following initiatives were sponsored by the Board in FY 19 as part of the Rx Cares Program:



PATIENT EDUCATION:

The Board launched a statewide patient education campaign in October 2018 to promote medication safety by educating patients on how to ensure they are taking medication safely and appropriately. Using the central theme of “**Stop. Ask. Be Safe. Your Pharmacist Knows**”, the campaign provided consumer education on:

- Appropriate ways to take prescription medication
- Tips for talking with a pharmacist
- Recognizing the effects and signs of prescription drug misuse
- Avoiding medication mistakes, and
- Proper medication disposal.

The patient campaign was developed and operated by Hubbard Interactive, the state approved vendor for media services, in consultation with the Board. The campaign included print, radio, billboard and social media advertisements and consisted of two flights which ran from October 15, 2018 to November 18, 2018 and January 7, 2019 to February 3, 2019.

Overall, the patient education campaign delivered an impact of over 23,000,000 impressions, including, an estimated:

- 3,728,488 radio impressions
- 9,277,736 billboard impressions (41 billboards were posted around the state with a concentration in rural areas)
- 1,846,100 newspaper impressions &
- 8,185,502 digital marketing impressions.

The campaign also included a television interview which aired on October 12, 2018 in the St. Louis market. A designated patient educational website was also established at rxcaresformo.org



Click here to visit the Rx Cares for Missouri website and get more information.

Rx Cares for Missouri Program



LICENSEE EDUCATION:

As part of the Rx Cares Program, the Board hosted the 2019 Missouri Pharmacy Patient Safety Conference in conjunction with the [Center for Patient Safety](#), a Missouri not-for-profit organization dedicated to reducing preventable harm in healthcare.

The conference provided expert training on:

- The Science of Safety: Creating a Patient Safety Culture
- Production Pressures & Pharmacy Pitfalls
- Interruptions, Distractions & Work Overload
- Case Studies in Safety: Technology, Process Engineering & More
- Blame vs. Accountability

Courses were taught by Center for Patient Safety instructors Eunice Halverson, MA, CPPS and Kathryn Wire, JD, MBA, CPPS, CPHRM. The program was free and open to all Board licensees/registrants; Board approved continuing education was provided.



MEDICATION DESTRUCTION:

Missouri continues its efforts to combat the opioid drug abuse epidemic impacting patients nationwide. One of the major sources of drug abuse is unused or unwanted medication that is accessible to the public. To address this issue, the Missouri General Assembly enacted § 338.142, RSMo, in 2017 which gave the Board authority to establish a drug take-back program for controlled substances in consultation with the Missouri Department of Health and Human Services. Funding to support the take-back program was appropriated in FY19.

The Board subsequently issued a Request for Proposal for operation of the take-back program. In compliance with state contracting procedures, a vendor contract was awarded in FY 19 to Sharps Compliance® to manage and operate the Rx Cares for Missouri Medication Destruction and Disposal Program. Pursuant to the program, the Board will provide funding for collection receptacles and pay to destroy medication at no cost to approved program participants. Participant applications will be available and accepted in FY 20 pending completion of required administrative rules.

